

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

CHARLESTON DIVISION

DEE MCBRAYER, et al.,

Plaintiffs,

v.

CIVIL ACTION NO. 2:12-cv-779

ETHICON, INC., et al.,

Defendants.

**MEMORANDUM OPINION AND ORDER
(Motions in Limine)**

Pending before the court are the plaintiffs' Motions in Limine [ECF Nos. 130, 132, 134, 136, 138, 140, 142, 144, 146, 148, 150] and the defendants' Motion in Limine [ECF No. 126].

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse (“POP”) and stress urinary incontinence (“SUI”). In the seven MDLs, there are more than 58,000 cases currently pending, approximately 28,000 of which are in this MDL, which involves defendants Johnson & Johnson and Ethicon, Inc. (collectively “Ethicon”), among others.

In this MDL, the court’s tasks include “resolv[ing] pretrial issues in a timely and expeditious manner” and “resolv[ing] important evidentiary disputes.” Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict*

Litigation in Products Liability Cases 3 (2011). The court seeks the assistance of the parties in completing these tasks by asking the parties to focus on discrete, important, or more relevant matters. Here, the court expected the parties to focus their motions in limine on “highly prejudicial statements in opening or closing statements or questions at trial that, once heard by the jury, cannot be easily cured by an instruction to disregard.” Pretrial Order No. 234, at 5 [2:12-md-2327 ECF No. 2314] (“PTO 234”). The court further cautioned that it would “not provide advisory opinions on the admissibility of evidence a party may offer at trial and [would] summarily deny those motions as premature.” *Id.*

a. The Plaintiffs’ Motion to Preclude Evidence Relating to the FDA (Motion in Limine No. 1) [ECF No. 130] & Motion in Limine Limiting FDA Related Evidence [ECF No. 144]

The plaintiffs ask the court to exclude evidence related to the FDA, including the FDA’s 510(k) process, arguing it is impermissibly irrelevant and prejudicial under Federal Rules of Evidence 402 and 403. Pls.’ Mem. Supp. Mot. Lim. 1–4 [ECF No. 131].

In short, the 510(k) process “does not in any way denote official approval of [a] device.” 21 C.F.R. § 807.97. The process is not focused on whether a device is safe; it is concerned with the device’s equivalence to another device. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996). Because the process does not speak to the safety or efficacy of any product, whether Ethicon products were approved through this process is irrelevant. Even if the 510(k) process were relevant, the court would exclude this

evidence under Rule 403. Any kernel of relevance is outweighed by “the very substantial dangers of misleading the jury and confusing the issues.” *In re C. R. Bard*, 810 F.3d 913, 922 (4th Cir. 2016) (affirming the court’s exclusion of 510(k) evidence).

Put simply, evidence of this sort is inadmissible and, in any event, does not survive a Rule 403 analysis. The court will not belabor the point here as it has already done so on several occasions. *E.g., Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 754–56 (S.D. W. Va. 2014). The court **GRANTS in part** the plaintiffs’ Motion in Limine [ECF No. 130] as to Motion in Limine No. 1 and in any instance where the defendants conceded to the plaintiffs’ Motion. The remainder of the plaintiffs’ Motion in Limine [ECF No. 130] is **DENIED without prejudice**.

The plaintiffs’ Motion in Limine Limiting FDA Related Evidence [ECF No. 144] is **DENIED as moot and duplicative**. *See supra* part (a); Mem. Op. & Order, Aug. 25, 2016, 6–8 [ECF No. 174].

b. The Defendants’ Motion to Exclude the January 2012 “522” Letters and Subsequent FDA Actions (Motion in Limine No. 2) [ECF No. 126]

The defendants ask the court to exclude evidence of the January 2012 “522” letters and subsequent FDA actions that would have applied to Ethicon devices if they had not been discontinued, arguing it is prejudicial and would require presentation of evidence on a collateral issue. Defs.’ Mem. Supp. Mot. Lim. 3–5 [ECF No. 127]. The plaintiffs do not contest this Motion. Pl.’s Mem. Response Defs.’ Mot. Lim. 3–4 [ECF No. 168]. Indeed, the court has excluded this same evidence on prior occasions. *See, e.g., Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, 2014 WL 6680356, at

*1 (S.D. W. Va. Nov. 25, 2014). The court **GRANTS** in part the defendants' Motion in Limine [ECF No. 126] on this point and in any instance where the plaintiffs conceded to the defendants' Motion; the remainder of the Motion is **DENIED without prejudice**.

c. Remaining Motions

The remaining Motions do not comport with PTO 234's requirement to focus on "highly prejudicial statements in opening or closing statements or questions at trial that, once heard by the jury, cannot be easily cured by an instruction to disregard" and are more appropriately handled by the trial court judge following remand or transfer at or before trial. PTO 234 at 5.

Accordingly, the following are **GRANTED** insofar as the defendants conceded and are otherwise **DENIED without prejudice**:

ECF No.	Motion
132	MOTION by Dee McBrayer, Timothy McBrayer in Limine No. 18 <i>Precluding Improper Arguments or Evidence of Dee McBrayer's Unrelated Medical Conditions and Unrelated Family Medical History</i>
134	MOTION by Dee McBrayer, Timothy McBrayer in Limine No. 19 to <i>Preclude Defendants From Defending Based on a Long History of Use of Polypropylene in the Human Body</i>
136	MOTION by Dee McBrayer, Timothy McBrayer in Limine No. 20 <i>Precluding Defendants From Improperly Arguing or Introducing Evidence Regarding Plaintiff Dee McBrayer's Pre-Existing Medical Conditions</i>

138	MOTION by Dee McBrayer, Timothy McBrayer in Limine No. 21 <i>Precluding Improper Arguments or Evidence Regarding the Risks of Alternate Procedures Which Plaintiff Did Not Undergo</i>
140	MOTION by Dee McBrayer, Timothy McBrayer in Limine No. 22 <i>Precluding Arguments or Evidence From Defendants From Telling the Jury About Symptoms of Prolapse</i>
142	MOTION by Dee McBrayer, Timothy McBrayer in Limine No. 23 <i>to Exclude Reference to Dee McBrayer's Difficult Childbirth</i>
146	MOTION by Dee McBrayer, Timothy McBrayer in Limine No. 26 <i>Establishing the Admissibility of Ethicon's Decision to Discontinue the Sale and Marketing of the Prolift</i>
148	OMNIBUS MOTIONS by Dee McBrayer, Timothy McBrayer in Limine Nos. 27-30 <i>to Preclude Improper Liability Defenses</i>
150	OMNIBUS MOTIONS by Dee McBrayer, Timothy McBrayer in Limine Nos. 31-32 <i>to Preclude Introduction of or Arguments Regarding This Court's Prior Judicial Opinions Regarding Plaintiffs' Experts and Treatment Plaintiff Did Not Undergo</i>

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: December 22, 2016



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE